



The DISCOVER study

Please read this leaflet. It explains the study so you can decide if you want to take part.

Quick read: key information

- As we age, many of us develop small changes to blood vessels in our brains. Mostly, these changes are not harmful, but for some people there is an increased risk of later health problems.
- Right now, we don't know the best way to prevent these health problems, so future research is needed to test new treatments.
- Before we can test new treatments, we need to find out the best way to contact patients to take part in future studies, and assess any changes in how patients are functioning over time. We need your help in to discover how to reduce the risk of serious health problem.
- We are inviting people who have had a brain scan in NHS Lothian and may have small changes to blood vessels.
- If you join, you will have one clinic visit (up to an hour and a half) and up to three short follow-ups over up to 18 months. There are no study medicines, extra scans, or blood tests.
- We will collect some information about your health, do short memory, mood and thinking tests, ask you about your day-to-day life, and make a short recording of your speech.
- We keep your information confidential and safe. We use it for research in public interest, following UK data protection law.
- You can withdraw from the study at any time and you do not have to give us a reason for your decision. Tell us if you also want us to stop using your health records for follow-up Taking part is your choice.
- Your NHS care will not be affected if you say no.
- If you have any questions about the study or are not sure why you've received this letter, please contact us.



1. Invitation to take part

You are invited to take part in the DISCOVER study. To help you decide, this leaflet explains:

- Why we are doing the research
- What taking part involves
- The possible risks and benefits
- How we use and protect your information
- Who to contact for questions or complaints

Talk to family or friends or our study team if you wish. Take as long as you need.

2. What is the DISCOVER study?

As we get older, small changes can happen in blood vessels in the brain and this is common. Mostly, these changes are not harmful, but for some this means a slightly higher chance of problems with memory or thinking and conditions like stroke in the future. Right now, we don't know the best way to prevent or treat this, so future research is needed to test potential treatments.

Before we can test new medication, we first need to learn how best to invite people to take part. We also need to make sure the information we collect is clear and helpful, so it can show us whether treatment makes a difference.

Sometimes, brain scans done for other reasons show these small age-related changes. We are writing to people who have had a brain scan in NHS Lothian, like yourself, and may have these changes to invite them to take part in our study.

We need your help to:

- Find the best way to identify and invite people with age-related changes in the brain to take part in research
- Make sure our approach is acceptable to participants
- See how many people join the study and choose to stay involved

3. Why have I been contacted?

We used one of two NHS-approved methods to find people who may be suitable:

- A secure, ethically approved search of NHS Lothian health records using a computer programme called “natural language processing”, supported by DataLoch (<https://dataloch.org/>). The NHS Lothian research team checked the list and sent letters.
- Referrals from doctors or other health-care staff.

You may be eligible because:

- You are 65 years or older
- You had a CT or MRI brain scan in the last 5 years which may show age-related brain blood vessel changes
- You have no record of stroke, TIA, dementia, Parkinson’s disease, multiple sclerosis, motor neurone disease, subdural haematoma, or metastatic cancer

If you are not sure why you received this letter, please contact us.

4. Do I have to take part?

- No. It is your choice.
- If you join, you can leave at any time, without giving a reason.
- Saying no, or leaving later, will not affect your NHS care or your legal rights.

5. What will happen if I take part?

You can speak with a study doctor or nurse and ask questions. If you decide to join, you will sign a consent form. You can do this in person, by phone, or online.

Your first clinic visit (up to an hour and a half)

A doctor or nurse will:



- Ask simple questions about your health, what medications you're on, and your day-to-day activities.
- Check your medical records for past and current health information.
- Check your blood pressure, measure your waist and hip, and do a simple test of your walking and balance. Record a short sample of your speech.
- Ask about your memory, mood, behaviour, and how you manage your everyday activities using brief questionnaires. This will help us understand your health now and compare any changes over time.

We will record:

- Your contact details, so we can stay in touch.
- Contact details for a close personal contact you choose (with their permission). We will only use this if we cannot reach you.
- Your Community Health Index (CHI) number (your unique NHS number in Scotland) and your GP details, so we can identify you correctly.

Follow-up by telephone

To see how your brain health is over time:

- We will repeat the speech recording by phone.
- We will send you a short questionnaire about your memory, thinking and day-to-day activities by post or email (your choice).

Timing:

- About 3, 6, and 12 months after your first visit.
- Each call should take no more than 20 minutes.
- We will also check your NHS Lothian electronic health records to see if there has been any changes in your health.

There are no study medicines, extra scans, or blood tests.

At the end of the study, we will thank you for your time. If during the study we identify new changes in memory and understanding, we will discuss with you and arrange a clinic appointment if you need one. We may also let your GP know.



6. Summary of your time and travel

- One clinic visit (up to an hour and a half)
- Up to three short follow-ups by phone and post/email over 12 months
- We will repay reasonable travel costs for the clinic visit.

You can call the study team at any time to ask questions. You can withdraw at any time and you do not have to give us a reason for your decision.

7. What are the possible benefits?

Your participation could improve research and care for people with changes related to ageing in the brain. We will check your blood pressure and do a simple test of your walking and balance which may help show if you are at risk of falling. We can then advise you if needed. You will have the opportunity to discuss your brain health with one of the study team and will be able to get information about healthy brain ageing. At the end of the follow up we can discuss any concerns with you.

8. What are the possible inconveniences or risks?

- Travel to the first clinic visit may be inconvenient.
- Completing follow-up questionnaires may take time.
- Some people may find it difficult to discuss ageing related brain changes. This might lead to anxiety. We are happy to discuss these worries with you at the appointment or by telephone. We can offer follow up to discuss your brain health in a clinic for people with ageing related blood vessel changes if you are worried or distressed.
- If you feel upset or worried at any point, please tell the study team. We will support you and can pause or stop the tests.

9. What if there is a problem?

- For questions or concerns about the study, please contact the study team using the details in your letter. We will do our best to help.
- You can also use the normal NHS Scotland complaints process.



- If something goes wrong and you are harmed because of someone's negligence, you may be able to claim compensation from NHS Lothian. You may have to pay your own legal costs.

10. What happens if I want to stop taking part?

- You can stop at any time, without giving a reason. Your medical care will not be affected.
- The study doctor may advise you to stop if a new health problem makes it safer to do so. They will explain why.
- If you stop the follow-up calls, we would like to keep collecting information about your health from NHS Lothian records or your GP until the end of the study. This helps us answer the research question. Tell us if you do not want this.
- If you withdraw from all parts of the study, please tell the research team. We will keep information collected before you withdrew.

11. How we use and protect your information

We follow UK data protection law (including GDPR and the Data Protection Act 2018) and the Caldicott principles. We keep your information confidential and secure.

Who is responsible for your data?

- Data controller: The University of Edinburgh and NHS Lothian.
- Contact for data protection queries: dpo@ed.ac.uk (University of Edinburgh Data Protection Officer).

What information we collect

- CHI number and GP details (to identify you correctly)
- Name and initials, date of birth, sex, ethnicity
- Years of education and occupation
- Address, phone number, and email
- Health information
- Results of your mood, memory and thinking tests, and speech recording
- Contact details for a close personal contact (with their permission)



Why we use your information

- To run and check the study
- To link with your NHS records for follow-up
- To analyse results and improve future research

Our lawful basis under UK GDPR:

- Article 6(1)(e) Public task (research in the public interest)
- Article 9(2)(j) Research with safeguards

Who can see your information

- Only trained, authorised study staff will access your identifiable data.
- People who do not need to know who you are will not see your name or contact details.
- Your data will be given a code number before analysis.
- Hospitals taking part may be asked to share information for official inspections by the study Sponsor or regulators.

Where and how your data are stored

- Personal details are stored in a secure, password-protected University of Edinburgh database during the study.
- Identifiable data are kept separate from health data and removed before analysis.
- We do not plan to transfer your identifiable data outside the UK. If this becomes necessary, we will put legal safeguards in place.

How long we keep your data

- The University of Edinburgh will archive study information about you for 20 years.
- De-identified (anonymised) information may be kept indefinitely for future research, so that we do not need to repeat this study.

Your choices and your rights

- You can stop taking part at any time. We will keep the information we have already collected.

- If you stop taking part, we would like to keep using your NHS Lothian records for follow-up. Tell us if you want us to stop.
- Because we need to manage the data in specific ways for reliable research, we may not be able to let you see or change the study data we hold about you.
- You can choose to allow us to store your contact details so we may contact you about other approved research in the future. This is optional. You can withdraw this at any time. If you agree, we may ask for your verbal consent to share your contact details with another research team within the University of Edinburgh and/or NHS Lothian.

You also have the right to complain to the Information Commissioner's Office (ICO) about how your data are handled: www.ico.org.uk

12. Data sharing

- We may share de-identified data with approved researchers to check results and carry out further research. Any sharing will use a data sharing agreement to keep your information safe.
- Researchers who analyse the data will not be able to identify you.
- Reports and publications will not include anything that could identify you.
- If new studies become available that may interest you and you have previously given your permission, we will contact you.

13. Results of the study

- We will publish the results in professional journals.
- We will share a plain English summary on our website: www.clinical-brain-sciences.ed.ac.uk/discover
- The study is registered at ClinicalTrials.gov: NCT06878430.
- If you wish, we can send you a newsletter with updates by email.
- No published results will identify you.

14. Who is organising and funding the research?

- Sponsors: The University of Edinburgh and NHS Lothian
- Funder: Chief Scientist Office, Scottish Government
- Study management: The University of Edinburgh
- Chief Investigator: Professor William Whiteley



There are no payments to you for taking part, but we will repay reasonable travel costs for the clinic visit.

15. Ethical review and insurance

An independent NHS Research Ethics Committee has reviewed this study and given a favourable opinion. All participants are covered by the University of Edinburgh's insurance policy.

Patients, carers, and members of the public helped design this study. A Patient and Public Involvement (PPI) panel, including people with experience of stroke, small vessel disease, and vascular dementia, reviewed this leaflet.

16. Who to contact

- For questions about the study, appointments, or travel costs: please use the contact details in your invitation letter.
- For concerns or complaints about the study: please contact the study team first. You can also use the NHS Scotland complaints process.
- For data protection queries: dpo@ed.ac.uk

Thank you for considering taking part in DISCOVER. Take your time to decide. If you have any questions, we are here to help.

To find out more:

Look at the DISCOVER website: www.clinical-brain-sciences.ed.ac.uk/discover

Email: loth.discoverstudy@nhs.scot

Telephone: 0131 465 9536